

AMENDMENT OF THE CLAIMS:

1. (Currently amended) A method of improving the stability performance of dry powder pharmaceutical compositions for inhalation therapy comprising inclusion of
~~The use of~~ particulate derivatised carbohydrates in said dry powder pharmaceutical compositions ~~for inhalation therapy in order to improve stability performance.~~
2. (Currently amended) A method of eliminating or reducing the detrimental effect on fine particle dose resulting from storage of a dry powder pharmaceutical composition for inhalation therapy comprising inclusion of ~~The use of~~ particulate derivatised carbohydrates in said dry powder pharmaceutical compositions ~~for inhalation therapy in order to eliminate or reduce the detrimental effect on fine particle dose caused on storage of said compositions.~~
3. (Original) A dry powder pharmaceutical composition for inhalation therapy comprising a pharmaceutically active agent, an excipient and a derivatised carbohydrate in particulate form.
4. (Original) A dry powder pharmaceutical composition according to claim 3 in which the derivatised carbohydrate is a mono or di-saccharide in which at least one hydroxyl group of the carbohydrate group is substituted with a hydrophobic moiety via either ester or ethers linkages.
5. (Currently amended) A dry powder pharmaceutical composition according to ~~claims 3 or 4~~ claim 3 in which the derivatised carbohydrate is a carbohydrate selected from fructose, glucose, mannitol, maltose, mannitol, trehalose, cellobiose, lactose and sucrose in which at least one hydroxyl group of said carbohydrate is substituted by a straight or branched hydrocarbon chain comprising up to 20 carbon atoms.
6. (Currently amended) A dry powder pharmaceutical composition according to ~~any one of claims 3—5~~ claim 3 in which the derivatised carbohydrate is selected from the group consisting of cellobiose octaacetate, sucrose octaacetate, lactose octaacetate, glucose pentaacetate, mannitol hexaacetate and trehalose octaacetate.

7. (Original) A dry powder pharmaceutical composition according to claim 3 in which the derivatised carbohydrate is α -D cellobiose octaacetate.
8. (Currently amended) A dry powder pharmaceutical composition according to ~~any one of claims 3-7~~ claim 3 in which the derivatised carbohydrate is present at a concentration of less than 10% of the total composition.
9. (Currently amended) A dry powder pharmaceutical composition according to ~~any one of claims 3-8~~ claim 3 in which the derivatised carbohydrate has an aerodynamic size in the range 1 - 20 μ m.
10. (Currently amended) A dry powder pharmaceutical composition according to ~~any one of claims 3-9~~ claim 3 in which one component of the excipient that has a particle size of less than 15 μ m (the fine excipient component) and another component of the excipient that has a particle size of greater than 20 μ m but lower than 150 μ m (the coarse excipient component).
11. (Original) A dry powder pharmaceutical composition according to claim 10 in which the fine and coarse excipient components are both lactose.
12. (Currently amended) A dry powder pharmaceutical composition according to ~~any of claims 3-11~~ claim 3 in which the pharmaceutically active agent is 6 α , 9 α -Difluoro-17 α -[(2-furanylcarbonyl)oxy]-11 β -hydroxy-16 α -methyl-3-oxo-androsta-1,4-diene-17 β -carbothioic acid *S*-fluoromethyl ester.
13. (Currently amended) A dry powder pharmaceutical composition according to ~~any of claims 3-11~~ claim 3 in which the pharmaceutically active agent is 6 α , 9 α -Difluoro-11 β -hydroxy-16 α -methyl-17 α -[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene-17 β -carbothioic acid *S*-fluoromethyl.
14. (Currently amended) A dry powder pharmaceutical composition according to ~~any of claims 3-11~~ claim 3 in which the pharmaceutically active agent is 3-(4-[[6-

((2R)-2-hydroxy-2-[4-hydroxy-3-(hydroxymethyl)-phenyl]ethyl}amino)hexyl}oxy}butyl)benzene sulfonamide.

15. (Currently amended) A dry powder pharmaceutical composition according to ~~any of claims 3-11~~ claim 3 in which the pharmaceutically active agent is 3-(3-{{7-((2R)-2-hydroxy-2-[4-hydroxy-3-hydroxymethyl)phenyl]ethyl)-amino)heptyl}oxy}propyl) benzenesulfonamide.

16. (Currently amended) A method of treatment or prophylaxis of respiratory disorders which comprise administering to a patient in need thereof a dry powder pharmaceutical composition according to ~~any one of claims 3-15~~ claim 3.

17. (Currently amended) A method of manufacture comprising inclusion Use of a dry powder pharmaceutical composition according to ~~any one of claims 3-15~~ claim 3 in the manufacture of a medicament for the treatment of respiratory disorders.

18. (Currently amended) An inhalation device containing therein a dry powder pharmaceutical composition according to ~~any one of claims 3-15~~ claim 3.

19. (Previously presented) An inhalation device according to claim 18 in which the dry powder pharmaceutical composition is released from a pre-metered unit medicament pack.

20. (Previously presented) A medicament pack for use in an inhalation device which comprises an elongate strip formed from a base sheet having a plurality of recesses spaced along its length and a lid sheet hermetically but peelably sealed thereto to define a plurality of containers, each container having therein an inhalable composition according to ~~any one of claims 3-15~~ claim 3.

21. (Previously presented) A medicament pack according to claim 20 wherein the strip is sufficiently flexible to be wound into a roll.

22. (Previously presented) A medicament pack according to claim 20 wherein the lid sheet and base sheet have leading end portions which are not sealed to one another.

23. (Previously presented) A medicament pack according to claim 22 wherein at least one of the said leading end portions is constructed to be attached to a winding means.

24. (Previously presented) A medicament pack according to claim 20 wherein the hermetic seal between the base and lid sheets extends over their whole width.

25. (Previously presented) A medicament pack according to claim 20 wherein the lid sheet may be peeled from the base sheet in a longitudinal direction from a first end of the said base sheet.

26. (Previously presented) An inhalation device for use with a medicament pack according to claim 20 ~~any one of claims 20—25 which comprises an inhalable composition according to any one of claims 3—15~~, said device comprising:

- (i) an opening station for receiving a container of a medicament pack being used with said inhalation device;
- (ii) means positioned to engage peelable sheets of a container which has been received in said opening station for peeling apart the peelable sheets, to open such a container;
- (iii) an outlet, positioned to be in communication with an opened container, through which a user can inhale medicament in powder form from such an opened container; and
- (iv) indexing means for indexing in communication with said outlet containers of a medicament pack in use with said inhalation device.

27. (Currently amended) A medicament pack comprising a circular carrier disc which has a plurality of pre-filled, hermetically sealed containers formed integrally therewith and arranged in a circle, each container containing an inhalable composition according to ~~any one of claims 3—15~~ claim 3, each container being puncturable to form a hole on each side thereof to allow in use, air to flow through the container to entrain the powder contained therein.

28. (Currently amended) An inhalation device ~~by which inhalable compositions according to any one of claims 3—15 may be administered to a patient~~ which comprises:

- (a) a housing,
- (b) a tray mounted and capable of moving within said housing,
- (c) a circular carrier disc medicament pack according to claim 27, said tray being adapted to receive said circular carrier disc medicament pack,
- (d) a plunger for moving said tray (via a plunger) adapted to receive a circular carrier disc medicament pack according to claim 27,
- (e) an air inlet (through which air can enter said device) and
- (f) an air outlet (through which a patient may inhale and receive said composition.

29. (Currently amended) A medicament pack comprising a piercable capsule which contains an inhalable composition according to claim 3 ~~any one of claims 3—15~~.

30. (Currently amended) An inhalation device by which inhalable compositions according to ~~any one of claims 3—15~~ claim 3 may be administered to a patient which comprises a body shell which has a nozzle at a forward end and which is open at the rear end, a sleeve fitted on the outside of the body shell and rotatable with respect to it, a means for retaining a piercable capsule according to claim 29 extending through the rear wall of the sleeve into the body shell, means for piercing said capsule when sleeve is rotated and a guard to ensure that the composition and not the pierced capsule, passes through the nozzle.

31. (Currently amended) An inhalation device by which inhalable compositions according to ~~any one of claims 3 to 15~~ claim 3 may be administered to a patient which comprises a nozzle, an air conduit connected to said nozzle for allowing a passage of air to be inhaled, a dosing unit comprising a storage chamber for the composition (which may also comprise a dosage indicating means) and a displaceable element for dispensing said composition from the storage chamber into the air conduit, a manoeuvring unit for displacing said element in relation to the storage chamber and optional deflector devices to provide accelerated airflow.